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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,310	02/12/2004	Keith B. Gorden	58232US004	5538

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EXAMINER	
ROBINSON, HOPE A	
ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,310	GORDEN ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 22-29* is/are withdrawn from consideration.

5)☒ Claim(s) *21* is/are allowed.

6)☒ Claim(s) *12 and 19* is/are rejected.

7)☒ Claim(s) *13-18 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/22/04;9/17/04;8/16/04*
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

2. Applicant's election without traverse of Group III (claims 12-21) on August 8, 2005 is acknowledged.

Claim Disposition

3. Claims 1-29 are pending. Claims 12-21 are under examination. Claims 1-11 and 22-29 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Information Disclosure Statement

4. The Information Disclosure Statement filed on August 16, 2004, September 17, 2004 and November 22, 2004 have been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Drawings

5. The drawings filed on February 12, 2004 have been accepted by the examiner.

Claim Rejections - 35 USC ∋ 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying a TLR-8 agonist, does not reasonably provide enablement for said method producing any cytokine or any co-stimulatory marker or any combination thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re*

Wands, 858 F.2d at 737, 8 USPQ2d at1404 (Fed. Cir. 1988). The factors most relevant to the instant invention are discussed below.

The amount of experimentation required to practice the claimed invention is undue as the claims encompass any cytokine or co-stimulatory marker or any combination thereof. The claim is directed to a method of identifying a TLR8 agonist wherein the TLR-8 mediated cellular response comprises NF-kB activation, the production of at least one cytokine, the production of at least one co-stimulatory marker or any combination thereof. Undue experimentation would be require to practice to claim method and produce any cytokine or co-stimulatory marker absent guidance from the instant specification. The art recognizes that there are several cytokines, however, is TLR8 capable of producing all possible cytokines? Gorden et al. (Journal of Immunology, 2005, vol. 174, pages 1259-1268) acknowledges that TLR8 agonists were effective in inducing pro-inflammatory cytokines and chemokines such as TNF-alpha, IL-12 and MIP-1-alpha. The breath of the claims encompass more than the art or the instant specification provides support for. This renders the claimed invention as unpredictable in light of the teaching in the art and the number of working examples provided in the specification. Thus, the claimed invention lacks adequate guidance to allow a skilled artisan to practice the claimed invention commensurate in scope with the claims.

The issue in this case is the breath of the claim in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make

and test position is inconsistent with the decisions of *In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).*

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claim, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to construct and test every cytokine or co-stimulatory marker to see if a TLR8 agonist has the desired effect of the claimed invention would constitute undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103 (a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c) and potential 35 U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

8. Claim 12 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Jurk et al. (Nature Immunology, June 2002, vol. 3, no.6, page 1), cited on IDS filed August 16, 2004.

Jurk et al. report that R-848 (imidazoquinoline resiquimod) is an agonist of TLR7/8. Although the reference is silent on the method steps as claimed in terms of exposing a TLR8 negative cell culture to a test compound, the claimed invention is obvious as such is merely a control to determine the effect of a compound in the presence or absence of TLR8. As Jurk et al. report an agonist of TLR8 absent evidence

to the contrary a control had to have been established to ascertain that R-848 confers responsiveness to TLR8, thus acts as an agonist of TLR8.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have a method for identifying a TLR8 agonist, because Jurk et al. report the identification of a compound that confers responsiveness to TLR8 (agonist). Although the reference is silent on "a negative control" *per se*, one of ordinary skill in the art knows that a "negative control" is necessary to have in experimental procedures when testing the presence or absence of an effect of a test compound on a subject. Further, the disclosure of Jurk et al. reported the effect of the compound on two different TLRs thus a comparison is established in the reference, as the TLR7 is not the same as the TLR8 thus can be viewed as a negative control. Thus, the claimed invention was obvious to make and use at the time it was made and was *prima facie* obvious.

Art* of *Record

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Saunder et al. (Antimicrobial Agents and Chemotherapy, December 2003, vol. 47, no.12, pages 3846-3852) teach the TLR8 agonist Resiquimod or R848, however, the reference is not considered to be prior art based on its date.

Conclusion

10. Claim 21 is free of the prior art. Claims 13-18 and 20 are objected to as depending from a rejected based claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner 10/28/05

HOPE ROBINSON
PATENT EXAMINER